Title 21 Vacancy Announcement
Supervisory Physician and DPV Division Director
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Pharmacovigilance (DPV)

Summary:

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

The Office of Biostatistics and Pharmacovigilance (OBPV) provides comprehensive statistical, pharmacovigilance, and epidemiological evaluation of data submitted to the Center in support of regulatory requirements. OBPV evaluates the safety and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, statistics, medicine, risk analysis, public health, genomics, and other scientific areas.

The Division of Pharmacovigilance (DPV) monitors the post-market safety of Center for Biologics Evaluation and Research (CBER) regulated biological products to inform regulatory decisions. DPV develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts and coordinates the Center adverse event reporting. DPV performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies, and Risk Evaluation and Mitigation Strategies (REMS) under the Food and Drug Administration Amendment Act (FDAAA). DPV reviews labeling supplements for safety-related label changes. Additionally, the Division reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

Overview:

Area of Consideration: FDA-Wide
Open & Close Dates: November 22, 2024 – November 29, 2024
Salary: Starting at $210,000 and is set to commensurate with education and experience
Band: F
Occupational Series: 0602
Duty Location: White Oak Campus, Silver Spring, MD
Remote Job: No

Telework Eligible: Yes – as determined by the agency policy.
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band F
Supervisory Status: Yes
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 8888

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.
Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Duties:

The incumbent serves as the Supervisory Physician and Division Director of the Division of Pharmacovigilance (DPV) within the Office of Biostatistics and Pharmacovigilance (OBPV) and manages daily operations of the Division. This position reports to the Director of OBPV. As the Division Director, the incumbent develops and implements clinical epidemiological procedures for analyzing post-marketing and case-control studies and collaborates with other CBER units in research and regulatory investigation. The incumbent manages daily operations of the Division and oversees the Division staff that conducts population-based epidemiological safety and efficacy studies using large medical bases in the FDA Sentinel system or those of federal partners such as the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration, and others.

Specifically, the Division Director will:

- Serve as the Director and supervises staff and oversees work focused on the clinical review and evaluation of adverse biologics reactions and CBER's post-marketing surveillance programs.
- Manage and foster clinical reporting of serious unexpected adverse experiences associated with biological products including vaccines by obtaining comprehensive information on voluntary case reports.
- Provide epidemiologic clinical analysis of adverse biologics reaction data and vaccine adverse experience data and develops recommendations concerning the need for additional studies or regulatory aspects of product safety.
- Coordinate effective and timely communication with review divisions and provides epidemiologic support to CBER's pre- and post-marketing safety programs and projects.
- Represent OBPV, CBER, and FDA in local, national, and international scientific conferences and meetings of professional societies in discussions of programs, policies, and research activities in the area of epidemiologic investigation of drug and vaccine safety and efficacy.
- Perform other duties as assigned.

Requirements:

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- One-year supervisory period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. *See Political Appointee FAQ - OPM for more.*

Qualifications:

Basic Qualification Requirements:

In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following ***requirements:***

- Education: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

  AND
- Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

- Possess a current, active, full, and unrestricted license or registration as a Physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.
- Have at least 7-10 years of experience with developing, maintaining, and analyzing national safety surveillance databases of adverse events to biological products.

- Ability to prioritize and make critical decisions.
- Skilled at building partnerships and collaborations with internal or external stakeholders.
- Knowledge and understanding of current FDA regulations, policies, and procedures pertaining to safe and effective drugs and biologics.
- Medical board certification or eligibility is recommended but not required.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Foreign Education: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. ***For further information, visit the U.S. Department of Education website for Foreign Education Evaluation.***

How you will be evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement: Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

Equal Employment Opportunity:

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.
Equal Employment Opportunity (EEO) for federal employees & job applicants.

Reasonable Accommodation:

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

How to Apply:

Please submit **electronic resume or curriculum vitae** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable)**, **latest PMAP (if applicable)**, **unofficial transcripts**, **Foreign Credit Evaluation (if applicable), copy of your active medical license/s (if applicable**), **copy of your board certification/s (if applicable)**, and **letter of interest (Word or PDF)** with ***"Title 21 CBER/OBPV/DPV Division Director"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through November 29, 2024**

Announcement Contact:

For questions regarding this Title 21 (Cures) position, please contact CBERHumanCapital@fda.hhs.gov.

The Department of Health and Human Services is an equal opportunity employer with a smoke-free environment.

FDA is an equal opportunity employer.